



Dear Cancer Center Directors and Administrators:

Enclosed please find the announcement of a special one-time award opportunity entitled, "Supplements for Imaging Response Assessment Teams in Cancer Centers" (*IRAT Supplemental Awards*). The main purpose of these awards is to facilitate the development of oncologic IRATs in Cancer Centers to advance the role of imaging in assessment of response to therapy.

The announcement details eligibility criteria and criteria for responsiveness of proposals. All Cancer Center investigators, their co-investigators, and clinical and basic scientists in other programs and departments of the institution are eligible. Each application must meet the specific responsiveness criteria and be approved for submission by the Cancer Center Director.

Please note that the one-time receipt date is June 6, 2005, and that a letter-of-intent to submit a proposal is due by May 6, 2005.

The NCI encourages you to share this opportunity with your co-investigators and collaborators, as well as with qualified potential investigators and collaborators in other departments. It is appropriate to share it with all individuals in your institution who are engaged in research that meets the responsiveness criteria on the first page of the announcement.

Please contact Dr. Carl Jaffe at the email address or phone number below if you have questions regarding this initiative.

Sincerely,

Linda Weiss, Ph.D., Chief
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**Supplements for Imaging Response Assessment Teams in
Cancer Centers
(IRAT Supplemental Awards)
Guidelines for Application, Review, and Award
(3/31/2005)**

Background

The National Cancer Institute (NCI) wishes to provide administrative supplements to Cancer Centers positioned and interested in establishing Imaging Response Assessment Teams (IRATs). The concept for Imaging Response Assessment Teams grew out of discussions within the Association of American Cancer Institutes (AACI) and between AACI and NCI. Three years ago the AACI established a Cancer Imaging Initiative to explore how cancer centers can partner more effectively with the National Cancer Institute, private industry, and other cancer research entities to develop new research and clinical trials opportunities in imaging. The AACI partnered with the American College of Radiology Imaging Network (ACRIN), a cooperative group sponsored by the Cancer Imaging Program, National Cancer Institute (CIP/NCI), to co-sponsor a special imaging workshop for cancer center directors and chairs of radiology. This workshop (October, 2003) identified barriers to productive collaboration by cancer centers and radiology departments and developed recommendations for the promotion of imaging studies in cancer research. Their recommendations included the short-term goal of establishing “radiology response assessment teams” comprised of radiologists and imaging scientists to participate in the initial design of therapy-based clinical trials. In addition, a similar recommendation for Imaging Response Assessment Teams was made at a workshop on biomarkers organized by the NCI, the FDA, and the MD Anderson Cancer Center on Feb 3-4, 2005 in Houston, Texas.

Purpose

These guidelines describe the application procedure for and review of administrative supplements to National Cancer Institute-designated Cancer Centers (*IRAT Supplemental Awards*) to establish oncologic Imaging Response Assessment Teams (IRATs) as formal shared resources.

IRAT Supplement Awards are intended to facilitate development of oncologic IRATs in Cancer Centers to advance the role of imaging in assessment of response to therapy. This initiative will increase the application of quantitative anatomic, functional, and molecular imaging endpoints in clinical therapeutic trials. IRATs should be capable of providing enhanced involvement in quantitative analysis, interpretation, and integration of imaging data in response to therapy trials, as well as regular dissemination and communication of these methods with IRATs at other institutions.

Further intention is to increase clinical collaboration between imaging scientists and oncologic investigators at Cancer Centers to identify new oncologic imaging research opportunities in clinical trials that warrant multi-center clinical investigations and integrate imaging data as potential biomarkers or candidate surrogate markers in

clinical therapeutic trials. The IRAT supplements are intended to strengthen the imaging team and its engagement in oncologic trials (e.g. MD and PhD personnel) but are not intended to finance the cost of imaging procedures in specific trials or to purchase imaging equipment other than minor computer and network communication instruments. Funding for up to 8 administrative supplement awards are envisioned at \$247,000/year total cost, for up to 3 years per site.

Applications considered responsive should include, but are not limited to, the following:

1. A plan for the establishment of the IRAT within the Cancer Center. This should include:
 - How the Cancer Center's plans for the establishment of the IRAT will be communicated to the appropriate investigators and staff,
 - A specific timeline for all work involved in the plan,
 - How the proposed IRAT would provide enhanced imaging engagement in current and future Phase I, II, and III clinical trials,
 - A description of the IRAT team. Institutional IRATs should be comprised of MD and/or PhD imaging experts from the participating institution and possibly an imaging research technologist. The number of team members at each institution will be a local decision but should include experts in various imaging modalities and cancer sites with a strong focus on quantitative methods. An IRAT should, in part, provide expertise in positron emission tomography (PET) and magnetic resonance (MR) imaging, along with identified specialists in conventional anatomic imaging of the body, neurologic, musculoskeletal, and genitourinary imaging, computer science, and informatics who would be available to serve on an *ad hoc* basis. An explanation of how each proposed IRAT member's participation would enhance the use of functional molecular imaging endpoints in investigator-initiated Phase I, II, and III therapy trials should be included.
 - A description of how the IRAT members will be integrated into the protocol planning process within a given Cancer Center. The best means to achieve this will likely be dictated by the local institutional environment. Hence, mechanisms to involve the IRAT members at the earliest possible time in the protocol planning and design should be provided in detail. This could involve, but is not limited to, having IRAT members sit on the local protocol review and monitoring committees; be members of Cancer Center programs; or participate in SPORE grants.
 - A description of an overall evaluation process, specifying metrics by which the progress toward the implementation of the IRAT shared resource may be judged.
2. The Cancer Centers should provide an estimate of the number of ongoing Phase I, II, and III clinical trials for the past 2 years (governmental, privately sponsored, and institutional) and an estimate of the number of those trials that contain some

- imaging component employed to assess response to therapy (e.g. not merely staging or eligibility)
3. A commitment to participate in image-sharing with the NCI caIMAGE-caBIG initiative (http://cancerimages.nci.nih.gov/caIMAGE/use_guidelines.html). For example, consent form processes to permit de-identified/anonymized data sharing and/or image transfer to NCI caBIG from clinical trials containing imaging would be viewed as integral to these processes.
 4. A plan for continued support of the shared resource when supplemental funds have ended.
 5. Demonstration of commitment from the radiology, nuclear medicine, or other relevant imaging departments to participate in this initiative.
 6. In Centers where this is feasible, a plan to integrate Image-Guided Interventional (IGI) sequential biopsy methods with quantitative imaging to support appropriate Phase II trials is highly desirable.
 7. In Centers willing to serve as the sub-contracting site for a *nationally-capable experienced Communications Coordinating Center (CC)*, a plan to sub-contract with a nationally-capable and experienced group that would provide communications and meeting coordination amongst the individual IRAT grantees is highly desirable.

Questions regarding the responsiveness of proposed projects to this initiative should be directed to the Program personnel listed below.

Eligibility

- Eligible applicants include Cancer Center MD or PhD staff or clinical investigators, their co-investigators, and clinical and basic scientists in other departments and programs of the institution.
- Each application must meet the above criteria for project responsiveness and be approved for submission by the Cancer Center Director.

Type and Number of Applications That May Be Submitted

A Cancer Center may submit **one** application.

Receipt Date

The receipt date for:

Letters of Intent is *May 6, 2005*

Applications is *June 6, 2005*

Application Review Process:

A committee of NCI program staff will evaluate the merits of the administrative supplement applications using external basic or clinical/translational consultants when additional expertise is needed. It is expected that up to eight awards will be announced by September 30, 2005

Allowable Costs

The request cannot exceed a maximum of \$247,000 in total costs (direct plus indirect) per participating Cancer Center annually for a period of up to three years. The total cost per site for 3 three years may not exceed \$741,000.

Reasonable expenses could include, but are not limited to, any of the following:

- Compensation of IRAT members for their percent effort. It is expected that each IRAT would involve some commitment of time from one or more radiologists or other imaging physicians, and some commitment of time from one or more PhD-level imaging scientists, computer scientists, or imaging informatics specialists.
- Support for a research coordinator, research nurse, data manager, and/or image analysis.
- Travel and expenses for IRAT members for 1 coordinating meeting annually.

***Note:** Direct imaging costs associated with trials should be borne by the sponsoring institution and not the IRAT initiative, and should be recharged at the research rate.*

Additional funding, up to \$25,000 annually for three years, not to exceed \$72,000 total costs, will be provided to one Cancer Center qualified and willing to sub-contract to a *nationally-capable experienced Communications Coordinating Center (CCC)* which would provide communications and meeting coordination amongst the individual IRAT grantees. That sub-contracted CCC should have a track record of coordinating similar communications needs of major cancer center clinical trials initiatives. Additionally, that CCC will need to submit a work plan that reflects the input of the grantees, NCI and other partners. This work plan must be approved by the NCI prior to award. The CCC will be responsible for the development and dissemination of education materials, convening of meetings/workshops, web-site design and development, and other communication support to facilitate the goals of the project and to increase integration of IRATs into the Cancer Centers

It is not the intent of these awards to fund large capital equipment or to duplicate resources already available within a Cancer Center. Investigators should make maximum use of resources already available within their institution.

All applicable NIH policies must be followed.

Letter of Intent to Submit an Application

To expedite the review process, you are requested to notify the Diagnostic Imaging Branch of the Cancer Imaging Program, Division of Cancer Treatment and Diagnosis, NCI of your intent to submit an application (s) for this administrative supplement. This notification should be provided either by email or letter by no later than May 6, 2005 to:

Barbara A. Galen, MSN, CRNP, CNMT, Program Director
NCI/DCTC/CIP/DIB
6130 Executive Blvd. MSC 7412
Room 6050
Rockville, MD 20852-4910 (Courier)
Bethesda, MD 20892-7412
bgalen@mail.nih.gov

The Letter of Intent (LOI) required to submit an application **MUST**: 1) be copied to the Cancer Center Program/NCI Program Director responsible for the applicants Cancer Center, 2) include the Cancer Center grant number, 3) include the full name, address, phone, and email contact information for the responsible NCI Program Director, and 4) briefly describe (one paragraph) the proposed approach to establish an IRAT and the responsiveness of the approach to the IRATs Supplemental Award initiative.

Note: No signatures are required on electronic files submitted as Letters of Intent (LOI). The documents must be in MS Word format and PC compatible. A contact phone number and email address for the project leader must be provided.

Application Procedures

1) Cover letter:

A cover letter should accompany each application and be addressed to Barbara Galen, Program Director, Cancer Imaging Program, NCI. The cover letter must: 1) request an *IRAT Supplemental Award*, 2) provide the Cancer Center grant number, 3) provide the full name and contact information for the Cancer Center Program, NCI Program Director responsible for the Cancer Center, and 4) be signed by the applicant's Cancer Center Director, the leader of the project, and the appropriate business official of the institution.

2) Where to send the cover letter and application:

The cover letter and 10 copies of each application should be sent to

Barbara A. Galen, MSN, CRNP, CNMT, Program Director
NCI/DCTC/CIP/DIB
6130 Executive Blvd. MSC 7412
Room 6050
Rockville, MD 20852-4910 (Courier)
Bethesda, MD 20892-7412
bgalen@mail.nih.gov

3) Format for the Application:

- Use the standard **face page** of the PHS 398 (09/2004) form and follow instructions accordingly. For Item 2, Check “yes” and provide the title “*IRAT Supplemental Awards*”. In Items 7A through 8B, denote the direct and total costs for the first year, as well as for the entire period of support. Total costs should not exceed those stated under Allowable Costs above. The Cancer Center Director and Business Official of the institution must sign the face page.
 - Use the standard **budget pages** of the PHS 398 (09/2004) application (form pages 4-6). Provide a budget justification for personnel, supplies, other expenses. List any additional sources of support for the initiative provided by the Cancer Center grant, research grants, or other outside entities such as pharmaceutical or device manufacturers.
 - Provide biographical sketches of key personnel, using the standard PHS 398 (09/2004) format.
 - Continuing with the PHS 398 (09/2004), in **15 pages or less**, provide a summary that includes the following:
 1. A detailed description of the short (up to 3 years) and long-term plans and commitment to establish and integrate the IRAT shared resource into the Cancer Center activities.
 2. Brief statement describing how the proposed plans are responsive to the *IRAT Supplemental Award* initiative.
 3. Documentation of available resources, facilities, laboratories, equipment, etc.
 4. Brief statement of the significance and innovativeness of approach to the plan for integration of the IRAT into the specific Cancer Center.
 5. Brief statement of compliance with NIH policy for gender and minority inclusion and accrual.
- 4) Additional required documentation: *since it is the intent of this initiative to award funds for immediate use, applications will not be reviewed until all required materials have been received.* These documents may be in the form of appendices and will not count toward the 15 page requirement noted above in item 3).
- The Cancer Centers should provide an estimate of the number of ongoing Phase I, II, and III clinical trials for the past 2 years (governmental, privately sponsored, and institutional) and an estimate of the number of those trials that contain some imaging component employed to assess response to therapy (e.g. not merely staging or eligibility)
 - Letter of commitment by the chief of the imaging service (e.g.: chair of radiology or nuclear medicine as the case may be)

- Letter of commitment from the institution outlining short and long-term support for the IRAT as a formal shared resource within the Cancer Center
- If the applicant site elects to be considered for selection as the site contract holder for the IRATs Communications Coordinating Center (CCC), the following is required:
 1. A letter of willingness to serve as the sub-contract holder, signed by the Cancer Center Director and appropriate business official.
 2. A qualifying statement for the nationally-capable and experienced organization that would be considered by the CC for sub-contract.
 3. Brief outline of a work plan the CCC would submit and how it would be integrated into the work of the overall IRAT initiative.

Review of the Application

A committee of NCI program staff will evaluate the merits of the administrative supplement applications using external basic or clinical/translational consultants, when additional expertise is needed, based upon the following review criteria:

- Scientific merit, innovation and significance of the Cancer Center plan for the establishment and integration of an IRAT shared resource into Cancer Center activities.
- Scientific expertise of proposed IRAT members.
- Feasibility of the proposed plan for integration of an IRAT into the Cancer Center activities and plans within three years or less.
- Evidence of the Cancer Center's past success in Phase I/II clinical trials initiation, accrual, completion.
- Inclusion of a plan to increase the proportion of Phase I and II clinical trials in which quantitative imaging response procedures will be incorporated.
- Adequacy of plans for long-term support of the IRAT program as a shared resource within the Cancer Center.
- Availability of imaging and network-computerized equipment required to implement an IRAT.
- Inclusion of a strategy for the establishment and dissemination of new imaging protocols or standards and the Center's willingness to share ideas and methods with other IRAT teams through communication mechanisms which will be provided by the Communications Coordinating Center (CCC).
- Willingness to develop future plans to align a portion of the IRAT effort with the goals and processes of the evolving NCI caIMAGE/caBIG as described at <http://cancerimages.nci.nih.gov/caIMAGE/index.jsp> and <http://cabig.nci.nih.gov/>
- Adequacy of an administrative infrastructure to manage the distribution and accounting of funds to be provided by the supplemental award.

- Adequacy of the plan to include minorities and underserved populations, to the extent possible, within the applicable eligibility criteria.
- For sites applying to serve as the sub-contract site for the Communications Coordinating Center,
 - Adequacy of an administrative infrastructure at the CC to manage the distribution and accounting of funds to be provided by the contracting process.
 - Adequacy of the qualifying statement of the CCC organization suggested by the CC.
 - Adequacy of the work plan summary to integrate the CCC activities across all IRAT grantee sites within the initiative.

Awards

It is the intent to have funding decisions made regarding funding within 90 days of the application receipt date based on recommendations by the NCI.